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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,040	07/24/2003	Michael Lebner	0156-2008US01	1249
7590	06/14/2005		EXAMINER	
Kevin M. Farrell Suite 350 One New Hampshire Avenue Portsmouth, NH 03801			LEWIS, KIM M	
			ART UNIT	PAPER NUMBER
			3743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/626,040	<b>Applicant(s)</b> LEBNER, MICHAEL	
	<b>Examiner</b> Kim M. Lewis	<b>Art Unit</b> 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/31/03</u> | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u>                   |

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement filed 10/31/03 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 6, 10-12, 18, 19, 23, 25, 29-31, 33, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,329,564 ("Lebner").

As regards claim 1, Lebner substantially discloses applicant's presently claimed invention. More specifically, Lebner discloses a two-component device for closing a laceration or incision, comprising: a first component (5) comprising a first adhesive-backed anchoring member and one or more first connecting members (15) extending from one edge thereof in a first direction, a second component (25) comprising a second adhesive-backed anchoring member and one or more second connecting members (35) extending from one edge thereof in a second direction generally opposite to the first direction, and adhesive means for attaching the one or more first connecting members to the second anchoring member and means for attaching the

one or more second connecting members to the first anchoring member, the attachment of the connecting members to the anchoring members forming attached and bridging portions of the one or more connecting members, the attached portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members (col. 5, lines 51-52 and col. 5, line 64-col. 6, line 1).

As to the recitations that the one or more first connecting members are “produced separately from the first adhesive-backed anchoring member” and that the one or more second connecting members are “produced separately from the second adhesive-backed anchoring member”, the applicant should note that in a product claim the manner in which the components are formed is not germane to the issue of patentability. The applicant should also note that the components of Lebner are capable of being formed separately.

As regards claim 4, note pulling elements (40, 45) and col. 5, lines 58-64.

Regarding claim 6, Lebner discloses that the pulling element and extensions of the connecting members are removable at the perforations (17, 37) following application of the device. The applicant should note that the extension of the connecting members is defined as the portion of the connecting member severed with pulling elements (40, 45).

Regarding claim 10, Lebner discloses that the device is constructed from a vapor-permeable (*i.e.*, allow for the exchange of air) material (col. 3, lines 5-15).

Regarding claims 12 and 14, in col. 1, lines 48-65, Lebner discloses that both

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the anchoring members and the connecting members are protected by release liners, and that the first and second anchoring members are protected by first and second release liners (col. 1, lines 48-65).

Regarding claim 11, note col. 1, lines 43-46 and col. 1, line 66-col. 2, line 2, which disclose adhesive means.

Regarding claims 18 and 19, note the disclosure of reinforcements at col. 2, lines 60- col. 3, line 4.

Regarding claim 20, mere use of the modified device of discussed above in the rejection of claim 1 above obviates the claimed invention. The applicant should note that manipulating the pulling elements for attachment onto the anchoring member such that the wound or laceration is closed, necessarily involves adjusting the position of anchoring members in both an x and y dimension.

Regarding claims 23, 25, 29-31, 33, 37 and 38, note the rejection of claims 4, 6, 10-12, 14, 18 and 19, respectively.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 2, 3, 5, 7-9, 13, 15-17, 21, 22, 24, 26-28, 32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebner.

Regarding claims 2 and 21, at col. 3, lines 5-15, Lebner discloses that the flexible elements, elongated connectors and pulling elements are produced from sheet stock. Lebner fails to teach that the connecting member and the anchoring members are produced from different sheet stock. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to produce the two components from different sheet stock in order to impart different physical characteristics to different parts of the device.

Regarding claims 3 and 22, note col. 2, lines 60-66, which discloses that the sheet stock can be elastic.

Regarding claims 5 and 7-9, Lebner fails to teach that the pulling elements are coded to enable user distinction, that the coding comprises an observable geometric distinction between the shape of the pulling elements and the shape of the anchoring members, that the coding comprises printed indicia enabling user distinction between pulling elements and anchoring members, that the coding on the pulling elements

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comprises distinguishing colors, or that the anchoring members are provided with one or more alignment indicators.

However, Lebner discloses at col. 4, lines 38-53, that the bandage can include wound closure visual alignment indicators, and further discloses at col. 5, lines 1-21, that the bandage can include indicia (e.g., color, graphic representations, etc.) for the purpose of indicating specific information to the user (e.g., tension).

In light of these disclosures, it would have been *prima facie* obvious to one having ordinary skill in that art at the time of invention to provide any portion of the Lebner bandage with indicia of various types (e.g., colors, shapes, printed material, etc.) in order to indicate any information.

Regarding claims 13 and 15-17, note the rejection of claims 5 and 7-9 above. The same rationale applies to claims 13 and 15-17. As such, the claims are not distinguishable over the prior art.

Regarding claims 24, 26-28, 32, and 34-36, note the rejection of claims 5, 7-9, 13 and 15-17 above.

### ***Double Patenting***

Claims 1-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,822,133 B2 ("the '133 patent") in view of U.S. Patent No. 6,329,564 B1 ("Lebner").

It is clear that substantially all the limitations of claims 1 and 20 of the present application are to be found in claims 1 and 7 of the '133 patent. The differences merely

amount to wording changes and that the one or more first connecting members are "produced separately from the first adhesive-backed anchoring member" and that the one or more second connecting members are "produced separately from the second adhesive-backed anchoring member". However, the applicant should note that in a product claim the manner in which the components are formed is not germane to the issue of patentability.

With respect to claims 2-19 and 21-38, the '133 patent fails to teach these limitations. However, Lebner either explicitly discloses these features or renders obvious these features. Applicant's attention is directed to the rejection of these claims above. The applicant should note that the same rationale for combining this reference above also apply in this double patenting rejection.

Claims 1, 4-20 and 23-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-18 and 20-34 of copending Application No. 10/625937 ("the '937 application"). Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that substantially all limitations of claims 1, 4-20 and 23-38 of the instant application are to be found in claims 1, 3-18 and 20-34 of the '937 application. The only limitation not present in claims 1, 3-18 and 20-34 of the '937 application is that the one or more first connecting members are "produced separately from the first adhesive-backed anchoring member" and that the one or more second connecting members are "produced separately from the second adhesive-backed anchoring



member". However, the applicant should note that in a product claim the manner in which the components are formed is not germane to the issue of patentability.

7. Claims 2, 3, 21 and 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/625,937 ("the 937 application") in view of Lebner.

As regards claims 2, 3, 21 and 22, note the double patenting rejections of claims 1 and 20 above. In further regards to claims 2, 3, 21 and 22, the '937 application fails to teach the two-component device of Claim 1 wherein the connecting members and the anchoring members are produced from different sheet stock or the two-component device of Claim 2 wherein the sheet stock used for production of the anchoring members is elastic.

Lebner discloses at col. 3, lines 5-15 that the flexible elements, elongated connectors and pulling elements are produced from sheet stock. Lebner fails to teach that the connecting member and the anchoring members are produced from different sheet stock. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to produce the two components from different sheet stock in order to impart different physical characteristics to different parts of the device.

This is a provisional obviousness-type double patenting rejection.

Claims 1, 4-20 and 23-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-

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19 and 21-36 of copending Application No. 10/626,783 ("the '783 application").

Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that substantially all limitations of claims 1, 4-20 and 23-38 of the instant application are to be found in claims 1, 3-19, and 21-36 of the '783 application. The only limitation not present in claims 1, 3-19, and 21-36 of the '783 application is that the one or more first connecting members are "produced separately from the first adhesive-backed anchoring member" and that the one or more second connecting members are "produced separately from the second adhesive-backed anchoring member". However, the applicant should note that in a product claim the manner in which the components are formed is not germane to the issue of patentability.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 3, 21 and 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 19 of copending Application No. 10/626,783 in view of Lebner.

As regards claims 2, 3, 21 and 22, note the double patenting rejections of claims 1 and 20 above. In further regards to claims 2, 3, 21 and 22, the '783 application fails to teach the two-component device of Claim 1 wherein the connecting members and the anchoring members are produced from different sheet stock or the two-component

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device of Claim 2 wherein the sheet stock used for production of the anchoring members is elastic.

Lebner discloses at col. 3, lines 5-15 that the flexible elements, elongated connectors and pulling elements are produced from sheet stock. Lebner fails to teach that the connecting member and the anchoring members are produced from different sheet stock. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to produce the two components from different sheet stock in order to impart different physical characteristics to different parts of the device.

Claims 1, 4-13, 17-20 and 23-32, 34 and 36-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 16-30 and 32-34 of copending Application No. 10/625,785 ("the '785 application"). Although the conflicting claims are not identical, they are not patentably distinct from each other because substantially all limitations of claims 1, 4-20 and 23-38 of the instant application are to be found in claims 1-12, 16-30 and 32-34 of the '785 application. The only limitation not present in claims 11-12, 16-30 and 32-34 of the '785 application is that the one or more first connecting members are "produced separately from the first adhesive-backed anchoring member" and that the one or more second connecting members are "produced separately from the second adhesive-backed anchoring member". However, the applicant should note that in a

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product claim the manner in which the components are formed is not germane to the issue of patentability.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 3, 14-16, 33 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/626,785 ("the 785 application") in view of Lebner.

As regards claims 2, 3, 21 and 22, note the double patenting rejections of claims 1 and 20 above. In further regards to claims 2, 3, 21 and 22, the '785 application fails to teach the two-component device of Claim 1 wherein the connecting members and the anchoring members are produced from different sheet stock or the two-component device of Claim 2 wherein the sheet stock used for production of the anchoring members is elastic.

Lebner discloses at col. 3, lines 5-15 that the flexible elements, elongated connectors and pulling elements are produced from sheet stock. Lebner fails to teach that the connecting member and the anchoring members are produced from different sheet stock. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to produce the two components from different sheet stock in order to impart different physical characteristics to different parts of the device.

With respect to the remaining claims the '785 application fails to teach these limitations. However, Lebner either explicitly discloses these features or renders obvious these features. Applicant's attention is directed to the rejection of these claims above. The applicant should note that the same rationale for combining this reference above also apply in this double patenting rejection.

This is a provisional obviousness-type double patenting rejection.

Claims 1, 4-20 and 23-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/625,936 ("the '936 application"). Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that the limitations of claims 1, 4-20 and 23-38 of the instant application are found in claims 1-34 of the '936 application. The only limitations not present in claims 1-34 of the '936 application is that the one or more first connecting members are "produced separately from the first adhesive-backed anchoring member" and that the one or more second connecting members are "produced separately from the second adhesive-backed anchoring member". However, the applicant should note that in a product claim the manner in which the components are formed is not germane to the issue of patentability.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 3, 21 and 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 18 of copending Application No. 10/625,936 ("the '936 patent") in view of Lebner.

As regards claims 2, 3, 21 and 22, note the double patenting rejections of claims 1 and 20 above. In further regards to claims 2, 3, 21 and 22, the '936 application fails to teach the two-component device of Claim 1 wherein the connecting members and the anchoring members are produced from different sheet stock or the two-component device of Claim 2 wherein the sheet stock used for production of the anchoring members is elastic.

Lebner discloses at col. 3, lines 5-15 that the flexible elements, elongated connectors and pulling elements are produced from sheet stock. Lebner fails to teach that the connecting member and the anchoring members are produced from different sheet stock. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to produce the two components from different sheet stock in order to impart different physical characteristics to different parts of the device.

This is a provisional obviousness-type double patenting rejection.

Claims 1 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of copending Application No. 10/938,163 ("the '163 application"). Although the conflicting claims are not identical, they are not patentably distinct from each other because it is

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clear that substantially all of the limitations of claims 1 and 20 of the instant application are found in claims 1 and 16 of the '163 application. The differences merely amount to wording changes and that the one or more first connecting members are "produced separately from the first adhesive-backed anchoring member" and that the one or more second connecting members are "produced separately from the second adhesive-backed anchoring member". However, the applicant should note that in a product claim the manner in which the components are formed is not germane to the issue of patentability of the device itself. Another difference is that the abstract of the instant invention recites a two-component device for closing a laceration or incision, while the '163 patent recites a two-component medical device. However, the applicant should note that the preamble is denied the effect of a limitation where the claim is drawn to structure and the portion of the claim following the preamble is self-contained description of the structure not depending for completeness upon the introductory clause.

This is a provisional obviousness-type double patenting rejection.

Claims 2-19 and 21-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of copending Application No. 10/938,163 ("the '163 application") in view of Lebner.

As regards claims 2, 3, 21 and 22, note the double patenting rejections of claims 1 and 20 above. In further regards to claims 2, 3, 21 and 22, the '163 application fails to teach the two-component device of Claim 1 wherein the connecting members and the

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anchoring members are produced from different sheet stock or the two-component device of Claim 2 wherein the sheet stock used for production of the anchoring members is elastic.

Lebner discloses at col. 3, lines 5-15 that the flexible elements, elongated connectors and pulling elements are produced from sheet stock. Lebner fails to teach that the connecting member and the anchoring members are produced from different sheet stock. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to produce the two components from different sheet stock in order to impart different physical characteristics to different parts of the device.

With respect to the remaining claims, the '163 application fails to teach the limitations recited therein. However, Lebner either explicitly discloses these features or renders obvious these features. Applicant's attention is directed to the rejection of these claims above. The applicant should note that the same rationale for combining this reference above also apply in this double patenting rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of U.S. Patent No. 6,831,205 ("the 205 patent"). Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that



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substantially all of the limitations of claims 1 and 20 of the instant application are found in claims 1 and 16 of the '205 patent. The differences merely amount to wording changes and that the one or more first connecting members are "produced separately from the first adhesive-backed anchoring member" and that the one or more second connecting members are "produced separately from the second adhesive-backed anchoring member". However, the applicant should note that in a product claim the manner in which the components are formed is not germane to the issue of patentability of the device itself. Another difference is that the abstract of the instant invention recites a two-component device for closing a laceration or incision, while the '163 application recites a two-component medical device. However, the applicant should note that the preamble is denied the effect of a limitation where the claim is drawn to structure and the portion of the claim following the preamble is self-contained description of the structure not depending for completeness upon the introductory clause.

8. Claims 2-19 and 21-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of the '205 patent in view of Lebner..

As regards claims 2, 3, 21 and 22, note the double patenting rejections of claims 1 and 20 above. In further regards to claims 2, 3, 21 and 22, the '205 patent fails to teach the two-component device of Claim 1 wherein the connecting members and the anchoring members are produced from different sheet stock or the two-component device of Claim 2 wherein the sheet stock used for production of the anchoring members is elastic.

Lebner discloses at col. 3, lines 5-15 that the flexible elements, elongated connectors and pulling elements are produced from sheet stock. Lebner fails to teach that the connecting member and the anchoring members are produced from different sheet stock. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to produce the two components from different sheet stock in order to impart different physical characteristics to different parts of the device.

With respect to the remaining claims, the '205 patent fails to teach the limitations recited therein. However, Lebner either explicitly discloses these features or renders obvious these features. Applicant's attention is directed to the rejection of these claims above. The applicant should note that the same rationale for combining this reference above also apply in this double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis  
Primary Examiner  
Art Unit 3743

kml  
June 12, 2005